

INVESTIGATING THE EFFECTS OF AN OPEN LABEL PLACEBO ON ROMANTIC  
BREAKUP RECOVERY: A FEASIBILITY STUDY

By

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### **Abstract**

This study examined the feasibility of an open label placebo experiment, investigating the effects of an open label placebo (OLP) on psychological recovery from a romantic breakup amongst college students at the University of Arizona. Previous research has shown that an OLP, wherein participants are aware they are receiving a placebo, can be successful in improving symptoms and various conditions such as IBS, ADHD, migraines, and sleep disorders. Participants were randomized into either the experimental group, where they were given a placebo pill as treatment, or the control group, where they solely participated in the study and answered questionnaires at each assessment period. Although all participants declined in their self-reported distress over time, there were no differences between the experimental and control groups in recovery from romantic breakups any of the four outcome assessments. Although this study is possible to conduct, it was not feasible for us due to the difficulty in participant recruitment. Because we did not have a budget to provide monetary compensation for participants upon completion of the study, there was no incentive for individuals to participate.

Romantic breakups are an extremely common occurrence and are regarded to be psychologically challenging (Larson & Sbarra, 2019). Although not everyone copes with romantic breakups in the same way, the experience of going through a breakup can be psychologically stressful, as well as socially destabilizing (Bonanno et. al., 2011; Sbarra, 2019). Multiple studies in the past have found associations between romantic breakups and increased anxiety, depression, and feelings of loneliness, betrayal, and rejection (Field, 2017). While some people going through romantic breakups experience acute distress that they struggle to recover from, others are able to suffer less intensely and for a shorter period of time. For those individuals that experience a greater amount of acute distress, as well as difficulty moving forward and accepting the separation, there are not many interventions that exist to help promote recovery from the romantic breakup.

The placebo effect works when a patient is given a treatment—usually an inert sugar pill—which has no known biological impact to the recipient. The overall idea behind the placebo effect is that because patients do not know whether they are receiving the treatment or the placebo, they still expect to experience improvement of their symptoms and their condition, whatever condition that may be. As a result of this expectation of improvement, the patient will typically see some amount of improvement in their symptoms and condition. Essentially, placebos work by setting expectations in a person's mind that the treatment they are receiving will improve their condition, causing their symptoms to subside. However, there are problems that come along with giving a placebo to a patient. Administering a placebo in a clinical setting without informed consent from the patient involves deception, violates patient autonomy, and threatens to undermine the trust within a professional-patient relationship (Gold & Lichtenberg, 2014).

A solution to these problems is an Open Label Placebo (OLP), which involves informing the patients that they are receiving treatment in the form of a placebo. The Open Label Placebo effect occurs when patients are told they are receiving a placebo as their form of treatment but are also given the information that placebo effects have been shown to be effective in improving symptoms and conditions for patients with various conditions. Ethical analyses have shown that the use of OLP does meet ethical standards of transparency and informed consent (Blease et al., 2021).

The use of OLP has shown to improve outcomes for various physical and psychological health conditions such as: knee osteoarthritis (Henriksen et al., 2022), irritable bowel syndrome (Kaptchuk et al., 2010), migraines (Kam-Hansen et al., 2014), cancer-related fatigue (Yennurajalingam et al., 2022), allergic rhinitis (Schaefer et al., 2016; Kube et al., 2022), chronic low back pain (Carvalho et al., 2016), ADHD (Sandler & Bodfish, 2008), menopausal hot flashes (Pan et al., 2022), depression (Schienle & Jurinec, 2022), sleep disorders (El Brihi et al., 2019), and emotional distress among people who viewed distressing pictures (Schaefer, 2023). Pan and colleagues (2022) examined the effects that a treatment of OLP would have on women experiencing hot flashes. When conducting in depth interviews with the women in the study, researchers found that women did not have high expectations about the placebo treatment, however they had an initially positive attitude towards the placebo and expressed “hope” and openness to see what happened in the end but did not necessarily expect symptom improvement. Throughout the study they were required to record hot flashes in a symptom diary, which showed to help the women feel less symptom burden. Many women felt as though placebos were the perfect treatment for menopausal hot flashes, as it is not a disease that one should be taking medications for, but taking an OLP helps one to proactively address symptoms they are

experiencing. Overall, researchers did see improvement in the participants that took an OLP for menopausal hot flushes. Kaptchuk and colleagues (2010) investigated the effects of an OLP on symptom improvement for patients diagnosed with irritable bowel syndrome (IBS). The experimental group receiving the OLP showed to have a higher mean of global improvement scores (IBS-GIS), reduced symptom severity, adequate relief, and improved quality of life, at both the midpoint and endpoint of the study. Overall, the study conclude that the open label placebos may be an effective method of treatment for IBS, however the researchers do point out that more research is needed to determine whether physicians can help patients using OLP.

Sandler and Bodfish (2008) studied the short-term efficacy, side effects, and acceptability of the OLP effect in the treatment of attention deficit hyperactivity disorder (ADHD). The treatment that the children of the study received was open label for the child, parents, and physician, however it was single blind for the teachers of the children. The three main outcomes measures used in this study were IOWA Conners parent and teacher scales, the Pittsburgh side effects rating scale (PSERS), and the Clinical Global Impressions (CGI) scale. The IOWA parent scores revealed that ADHD behavior remained about the same when the medication dose was reduced with placebo, however ADHD behavior deteriorated when the medication dose was reduced without placebo. The IOWA teacher scores revealed no significant differences between the two conditions. For the CGI, there was a significant difference between the conditions: 50% dose and the 50% dose along with the placebo. Results of this study indicated that OLP treatment was acceptable and effective in treating some children short term for ADHD.

Thus far, there have been three meta-analyses done to examine the efficacy of OLP. Charlesworth and colleagues (2017) estimated the beneficial effects of OLP compared to the control group who received no treatment. Results from this meta-analysis suggested significant

benefits for individuals in the experimental group. A second systematic review and meta-analysis provided similar evidence suggesting benefits of an OLP compared to a no-treatment control group (von Wernsdorff et al., 2019). Finally, a third meta-analysis done by Spille and colleagues (2022) similarly revealed that OLP does appear to be effective when examined in various experimental studies. However, the researchers do point out that because there are few studies that examine OLP, there is still further research that needs to be done.

### **The Present Study: An OLP for Romantic Breakups**

Research on the effects of open label placebos is still in its beginning stages. Although there are multiple studies showing that OLP has been effective in treating various conditions, more research is needed to determine what conditions OLP is effective for and for what other issues it can be useful. To our knowledge, our study is the first to study the impact of an OLP for people struggling with a romantic breakup. In this honors thesis, I apply the topic of OLP work to the study of non-marital romantic breakups. Our study works to uncover whether or not an open label placebo has a significant impact on the recovery of a romantic breakup. The main hypothesis states that an open-label placebo (experimental condition) will improve the recovery process more than simply participating in the study and answering questionnaires (control condition). The simple assessment of emotional well-being after a breakup, which constitutes the control condition of our study, has itself shown to improve recovery through simple participation in the research paradigm (Larson & Sbarra, 2019). We anticipate that the results from our study will help further the research into the efficacy of open label placebos for treating emotional distress. We also hope that this research allows steps to be taken to discover possible interventions for recovery of romantic breakups.

### **Methods**

## Participants

Participants for this study were undergraduate college students at the University of Arizona who reported experiencing a romantic breakup (of a relationship lasting at least three months) within the prior 6 months. Forty four ( $N = 44$ ) participants completed at least one study visit, 21 randomly assigned to the control condition and 23 randomly assigned to the experimental condition. The study included 7 participants who identified as men, 36 women, and 1 as transgender. On average, participants were 19.75 years of age ( $SD = 2.62$ ), and 63% of the sample reported being freshman in college. The majority of the participants (63%) identified as White and 10% identified as Hispanic, with the remainder as Black and Hispanic. Participants reported having been in the relationship, on average, 18.2 months prior to the breakup ( $SD = 14.39$ ), and having separated from their partner, on average, 4.2 months prior to the breakup ( $SD = 2.96$ ). Overall, the sample was equally divided among people who indicated that they made the final decision to end the relationship (vs. their partner making the final decision to end the relationship). Among the participants who began the study, 16 of the 21 participants (76%) who were assigned to the control condition completed all five study visits and 16 of the 23 participants (69.5%) who were assigned to the experimental condition completed all five study visits.

## Procedures

To begin participant recruitment, the lead researcher is given results from a mass survey listing University of Arizona students who may be eligible to participate in the study. This screening questionnaire was created via RedCap. From there, the lead researcher sent out emails to these students that include a link to a screening survey, which further investigates their eligibility in the study. This email with the screening survey link is sent out a total of 3 times to

each person, giving them ample opportunity to respond and fill out the survey if they are interested in participating. If individuals answer both that their relationship lasted longer than four months and ended less than six months ago, then they are considered to be eligible to participate in the OLP study. For each new eligible individual, an identification number is assigned, and they are randomized into one of two groups, the experimental or control group. The participants are then assigned to a research assistant, who then reaches out to them to set up a time for the initial study meeting.

Once the individual is assigned to a particular research team member, they are sent an email thanking them for their interest in the study and are given a link to pick a time for the initial meeting. If they do not respond within 5 days, they are sent this email again. The individual is sent this email a total of 3 times before they are considered a dropout. If they do respond and pick a meeting time, they are sent a confirmation email for the initial meeting time they have selected. As a courtesy to all participants and a strategy to keep participants committed to the OLP study, they are sent a reminder email one day prior to each of the 5 meetings.

Researchers of the OLP study meet five times with each participant to whom they have been assigned. The study assessments occurred at baseline, then once weekly for four more sessions. All study meetings are done virtually via Zoom. During each of the five Zoom meetings, participants are welcomed to the meeting by the research assistant. The research assistants explain the instructions on the first meeting, and during all subsequent meetings offer to read through the instructions once again, if the participant needs a reminder of what is to be done. At each of the five Zoom meetings, participants in both conditions perform a Stream of Consciousness (SOC) task and fill out a series of questionnaires assessing their thoughts and feelings about loneliness, depression, self-concept, and the impact of the breakup regarding their



recent romantic separation. All measures are administered repeatedly over the course of four weeks to assess the change over time during the recovery process of the romantic breakup. In addition to the SOC task and the series of questionnaires, the participants in the experimental condition take an open-label placebo pill by mouth once a day. Participants in the experimental condition are told that the pills they are taking are a placebo, hence the term “open label.” They are also informed that placebos work by improving “mind-body healing processes” and tend to shape expectations for improvement of symptoms and conditions overall.

Once these meetings are completed, research assistants save audio recordings of the meetings, so that they can be listened to later if necessary. Research assistants also ensure that the study participants have completely filled out each of the questionnaires completely before the meeting has ended. When a participant has completed the study, they are then sent a debriefing form that completely explains to them the present study and what each of the conditions entailed. At the end of the debriefing form, there are two multiple choice questions asking what the main topic of the research was, and what the focus of the study was. The study participant emails the research assistant the answers to these questions. Once this is complete, the participant receives their three credits in the SonaSystem, as a reward for completing the study through the end.

## **Measures**

**UCLA Loneliness Scale.** The Revised UCLA Loneliness Scale is used to measure a person’s subjective feelings of loneliness and feelings of social isolation. Respondents answer 4 questions regarding loneliness and feelings of social isolation using a scale of 1 to 4, where 1 is “Never,” and 4 is “Always.” Sample questions used include, “How often do you feel alone?” and “How often do you feel isolated from others?” A higher score indicates a greater amount of self-reported loneliness and social isolation.

**Impact of Events Scale – Revised.** The Impact of Events Scale – Revised (IES-R) is used to measure participant’s self-reported responses to stressful events. This measure assesses various dimensions of responding after a stressful event, which include intrusion, hyper-arousal, and avoidance. Participants report their degree of distress over the past 7 days to 22 different difficulties that people sometimes experience after stressful life events using a scale of 0 to 4, with 0 being “Not at all,” and 4 being “Extremely.” Sample items include, “I had trouble staying asleep,” “I felt irritable and angry,” and “Pictures about it popped into my mind.” Higher scores indicate a greater amount of self-reported emotional distress following the romantic breakup.

**Inventory of Complicated Grief.** The Inventory of Complicated Grief (ICG) is a 15-item factor-analytically derived measure of complicated grief. Respondents with higher scores are associated with higher levels of depression and emotional distress. Participants indicate how they feel regarding given events with a scale from 1 (rarely) to 5 (always). Sample items include “I feel I cannot accept the relationship ending” and “I feel that life is empty without my past relationship/partner.”

**Patient Health Questionnaire-9.** The Patient Health Questionnaire-9 (PHQ-9) is a measure used for the screening, diagnosing, monitoring, and measuring of the severity of depression. The PHQ-9 asks respondents to indicate how often, in the past 2 weeks, they have been bothered by 9 different problems. Respondents use a scale of 0 (not at all) to 3 (nearly every day). A final question asks respondents “If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?” Responses for this final question include, “Not difficult at all,” “Somewhat difficult,” “Very difficult,” and “Extremely difficult.” A higher score for the PHQ-9 indicates more severe depression.

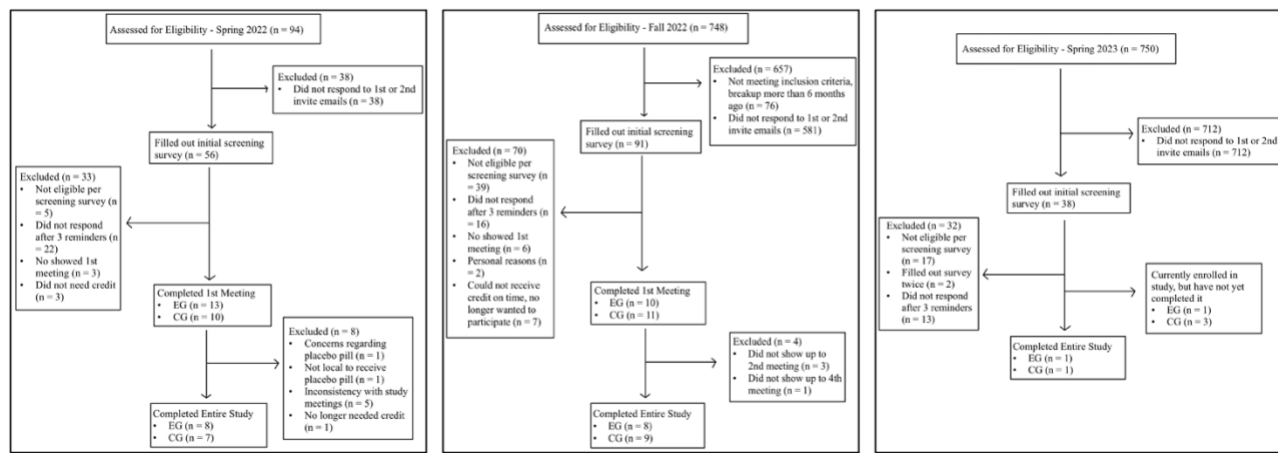
## **Data Analysis**

The goals of this study were to examine the feasibility and acceptability of randomly assigning participants to an OLP condition and assessing psychological adjustment to the romantic breakup over time. Because this is a pilot study, we are not adequately powered to detect significant differences between participants in the OLP and control conditions over time. Nevertheless, we explored a series of multilevel change models for each of the four primary outcomes to examine whether participants in the OLP condition would experience faster declines in separation-related emotional distress.

## **Results**

We actively recruited participants over the course of three academic semesters beginning in Spring 2022 and ending in Spring 2023. As shown in the CONSORT diagrams illustrated in Figure 1), each semester began with identifying a group of potentially eligible participants from the Psychology Department Mass Survey. Potentially eligible participants were those students who completed the mass survey and indicated that they has experienced a romantic breakup in the prior 6 months. Across the three semesters, 1,592 individuals were potentially eligible to participate with us and were sent the initial screening survey to further determine eligibility. Across the three semesters, of these participants sent the screening survey, 180 filled the survey out: 56 in Spring 2022, 91 in Fall 2022, and 33 in Spring 2023. At the end of Spring 2022, there were 8 participants in the experimental group who completed the study, and 7 participants in the control group who completed the study. At the end of Fall 2022, in the experimental and control groups, there were 8 and 9 participants who completed the entire study, respectively. Nearing the end of Spring 2023, there is 1 participant in each the experimental and control groups that have

completed the study. All in all, we were only able to enroll approximately 3 participants for every 1,000 we contacted.



*Figure 1.* Consort diagram revealing participant enrollment, dropouts, and completion through the entirety of the study.

Descriptive statistics for the four outcome variables at baseline are reported in Table 1.

Overall, participants reported relatively moderate breakup-related distress. For example, on the IES scale, participants reported a mean value of 1.38, which is roughly equivalent to reporting a “little bit” of separation-related emotional distress on the scale (reported range from 0 to 4). This pattern of moderate emotional distress was relatively consistent across the primary outcome variables.

**Table 1.** Descriptive Statistics and Bivariate Correlations of Study Variables

Variable	1	2	3	4	Mean	SD
1 - UCLA	--				2.60	.76
2 - IES	.53**	--			1.39	.73
3 - ICG	.52**	.74**	--		2.54	.78
4 - PHQ-9	.69**	.68**	.57**	--	1.86	.57

To examine change in the four primary outcome variables, we used a series of multilevel regression models, the results of which are depicted below. In the first model, we examined the main effect of time, which assess the degree to which participants reported significant declines in their separation-related distress over the study period (Table 2, Model 1). In the second series of models, we added the Time X Group interaction, which is the key test of the focal hypothesis that participants in the OLP condition would experience greater reductions in separation-related distress over the study period compared to participants in the control condition (Table 2, Model 2). As shown in Table 2 (Model 1), I observed significant decreases in all four of the primary outcomes over time. The mean trajectories of the outcome variables are displayed in Figure 2. The results of these analyses indicate that participants reported significantly less separation-related distress as the study progressed, which reflects general improvement in their adaptation to the breakup. I find no support that participant in the OLP condition declined faster in their distress relative to participants in the control condition. As shown in Table 2 (Model 2), none of the four Time X Group interactions were significantly different from zero.

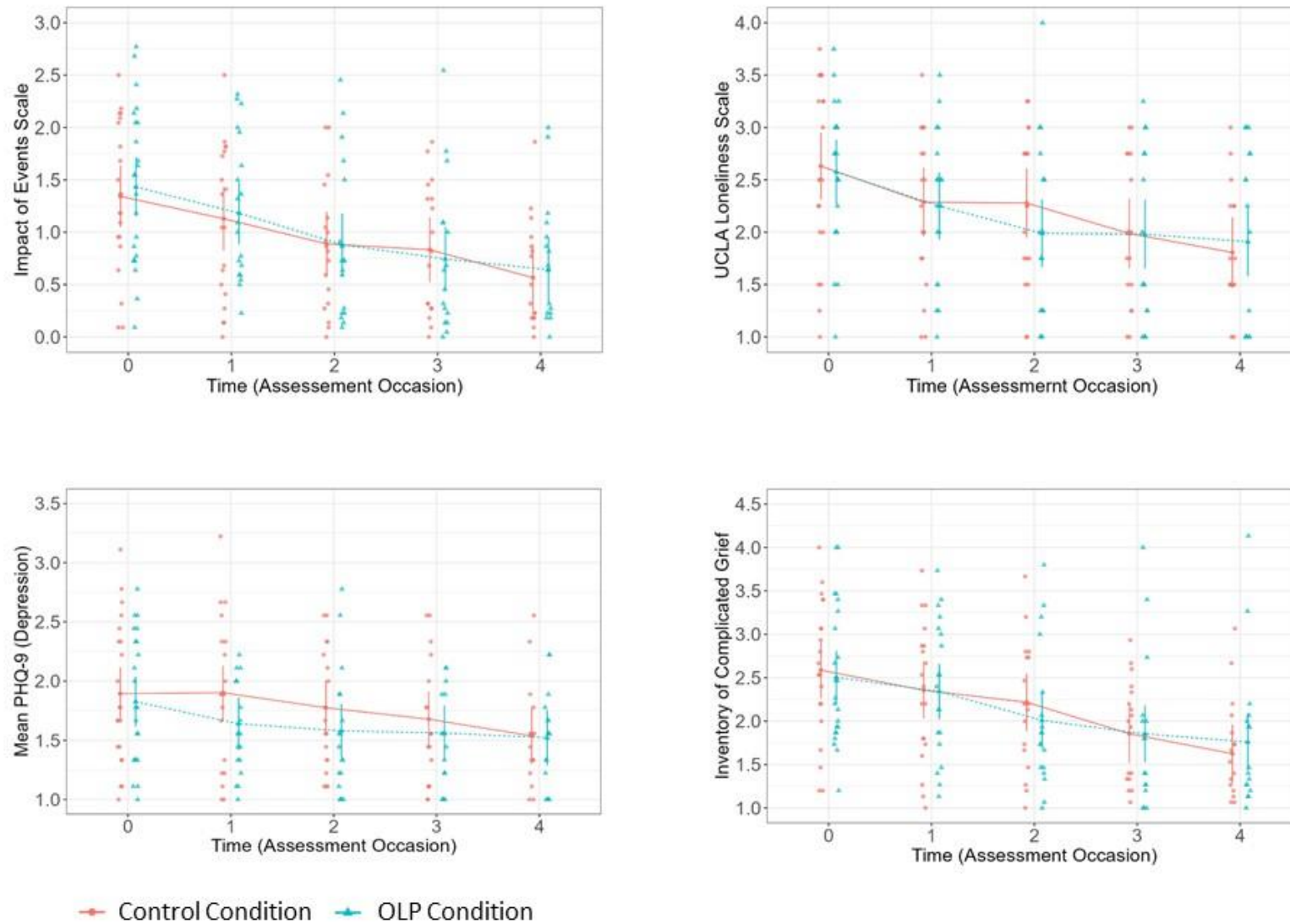
### **Acceptability and Feasibility Assessment**

As noted above, 16 of the 23 people assigned to the OLP condition completed all five study assessments, and this was roughly equivalent to the rate of completion among the control participants. Among these 16 people, nine reported having forgotten to take the OLP pills on at least one occasion (the modal number skipped was on one occasion, and the maximum number was on 5 occasions). Regrettably, I did not collect open-ended data about participants' impressions of taking the OLP and have no specific, qualitative information about whether participants' believed the act of taking the OLP played a role in their adjustment to the separation.

**Table 2.** Multilevel Model Results for Four Primary Study Outcomes

	<u>Model 1</u>				<u>Model 2</u>		
	<i>b</i>	<i>SE</i>	<i>t</i>		<i>b</i>	<i>SE</i>	<i>t</i>
<u>Loneliness</u>							
Intercept	2.54	.11	23.58***		2.59	.16	16.72***
Time	-.19	.03	-7.29***		-.20	.04	-5.58***
Group	--	--	--		-.11	.21	-.49
Time X Group	--	--	--		.03	.05	.57
<u>Impact of Events</u>							
Intercept	1.36-	.11	12.71***		1.33	.15	8.59***
Time	-.20	.03	-6.90***		-.19	.04	-4.68***
Group	--	--	--		.06	.21	.29
Time X Group	--	--	--		-.01	.06	-.23
<u>Complicated Grief</u>							
Intercept	2.55	.12	22.03***		2.61	.17	15.62***
Time	-.22	.03	-7.60***		-.24	.04	-5.79***
Group	--	--	--		-.11	.23	-.48
Time X Group	--	--	--		.03	.06	.57
<u>Depression</u>							
Intercept	1.85	.08	22.28***		1.94	.12	16.26***
Time	-.08	.02	-3.91***		-.09	.03	-2.88
Group	--	--	--		-.16	.16	-.95
Time X Group	--	--	--		.008	.04	.18

Note. Model 1 = Change over time without treatment condition; Model 2 = Change over time, including focal Time X Treatment Group interaction.  $P < .05$  \* ;  $P < .01$  \*\* ;  $P < .001$  \*\*\*



*Figure 2.* Mean trajectories of four primary study outcomes across the five assessment occasions as a function of participant study condition.

## Discussion

The goal of the present study was to investigate whether an open label placebo (OLP) would promote recovery and decrease self-reported emotional distress following a non-marital romantic breakup. Participants in the experimental condition were given a placebo pill that they took each day during their one-month participation in the study, while those in the control condition completed all aspects of the study with the exception of taking the OLP each day. This study included four primary outcome variables: UCLA Loneliness scale, IES-revised, ICG, and PHQ-9, in order to quantitatively measure recovery and distress after a romantic breakup.

Overall, participants in the study reported significantly less separation-related distress as the study went on. I observed a significant decrease in all four primary outcome variables investigated within the study. Unfortunately, there was no support that the participants in the experimental condition saw a faster decline in distress compared to participants in the control group. There were no significant time x group interactions found.

Throughout the entirety of the study, the most difficult part was finding and recruiting individuals to participate. The present study did not have a budget to provide study participants with monetary compensation for their participation. Students who needed research participation credit were eligible to receive 4 research credits in the Sona System upon completion of the study. However, this did not prove to be enough incentive for people to want to participate in the study. The present OLP study to investigate recovery after a romantic breakup is feasible and has been shown that it can be done. However, to get the sample size needed, the research team would need to get funding in order to be able to provide study participants with monetary compensation. This would give people motivation to join the study, as well as continue through all 5 Zoom meetings to finish the entirety of the study.



Although our sample sizes were small-- 17 in the OLP conditions and 17 in the control condition—these samples are not far below those observed in other OLP reports. For example, a previously mentioned study that investigated the OLP effect on patients with depression had a total sample size of 60 participants (Schienle & Jurinec, 2022). Another study that investigated the effect of an OLP on children with ADHD used a total sample size of 26 participants (Sandler & Bodfish, 2008). If the OLP effect was large, then it would be possible to reveal it in a smaller sample size.

Overall, being the lead RA on this study has taught me a lot and allowed me to gain a lot of knowledge of how research works. Firstly, being able to lead other research assistants in this project has given me leadership skills and has taught me to delegate tasks. Delegating has always been hard for me, but with the workload for this study it was something I had to learn to do because I would not be able to do it all on my own, and I wanted to ensure the other research assistants were getting ample experience in research. Working as the lead RA has also taught me how research works and what goes into studies behind the scenes. Being able to see the research go from study meetings where participants answer a series of questionnaires, to the questionnaires being turned into quantitative measures that allows us to investigate distress after a romantic breakup was very interesting.

One aspect of research that surprised me was how difficult participant recruitment was. When reaching out to potential participants, I would send out mass emails to 100-200 people at a time. I would do this every couple of weeks in order to constantly have new participants. At times, of these 100-200 individuals, I would have 3-4 people fill out the screening survey, indicating whether they were eligible to participate in the study. This difficulty in participant recruitment led to the small number of individuals who completed the study.

In conclusion, the initial hypothesis stating that an OLP would promote more recovery than just simply participating in the study was not supported. There was no significant difference between the recovery of the participants taking the OLP, when compared to the individuals in the control condition. Although this study is feasible, we were not able to recruit a large sample due to our lack of budget and lack of ability to provide individuals with enough incentive to join and participate in the study.

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